

Remarks/Arguments

This amendment is in response to the Office Action dated April 40, 2006.

Claims 1-3, 6-13 remain in this application. Claims 4, 14 and 15 have been canceled. Claim 5 was previously canceled.

Claims 1-3, 6-13 have been rejected under 35 USC 103(a) over Svensson (US 4,306,705)

Applicant disagrees.

The present invention relates to a sterile connector formed of at least two parts, the connector and the coupling. Both the connector and the coupling use sterile sealing plugs to close off the sterile interior of the components from the outside environment. The connector has a port that has two openings and a means for supporting the sterile plug when in a closed position. The port is capable of being in one of three positions, closed with its sealing plug blocking the way, partially opened, where the sealing plugs of the mating connector and coupling device are placed into the first opening of the port and fully opened where the connector and coupling device are in fluid communication with each other via the second opening. The exposed surfaces of the two plugs are mated to each other and isolated in the first opening of the port such that only sterile components contact each other during any movement. In this way sterility is assured with the claimed device and process.

The reference only teaches a port capable of being in one of two positions, closed or open and only having one opening. Additionally, it fails to teach or suggest the use of a sterile plug in that port, which is supported by the port when in the closed position as is required by the present claims.

The office action fails to provide any motivation as to why one of skill in the art would have found it obvious from the reference, absent the teachings of the present invention, to make a port having two openings, one of which is for receiving the plugs from the two or more components and the other for forming a fluid pathway through the device or a port that is capable of being in one of three positions or why one of skill in the art would use a sterile plug in the port when in a closed position as is required by the present claims. Applicants believe there is no such motivation from the reference as it works in an entirely different manner from the present invention. The port of the reference uses a recess 16 when in the closed position. It acts as a barrier but is not a sterile plug as is claimed by the present invention.

Moreover as to the process claims such as claims 2 and 12, the reference fails to teach or suggest each and every step of the presently claimed invention. In particular, it fails to teach moving the port between the three positions as claimed. The reference only teaches two positions for the port as shown in its Figures 3 and 4. Additionally, the reference fails to teach or suggest the use of rotational movement for some of the movements as is required by claim 12. It also fails to teach or suggest moving two plugs into the first opening during a partially opened position.

The office action recognizes that the cited reference does not teach using sealing barrier plugs. Instead, it uses "packaging, barrier covers 10 or filters" to create a sterile barrier within the flow passage and that it would have been obvious to one of ordinary skill in the art to place sterile barriers such as filters in the flow passage of the Svensson valve in order to maintain sterility.

Packaging would no longer be sterile once it is opened for use. The barrier covers 10 are dust guards mounted on the ends of the slide 7 and perform a function similar to that of the perimeter

seal 34 of the present invention. The reference uses a linear seal such as the valve 3. Such seals are difficult to maintain in a sterile condition and are easily dislodged.

The Examiner has cited no art that shows such a plug, and therefore provided no basis for concluding that it would have been obvious to somehow modify the reference to arrive at the claimed invention.

Additionally, the use of filters in the reference fails to teach or suggest the claimed invention which uses sterile plugs to seal the entrance points of the components until a sterile connection can be made. Moreover, the filters would be exposed to the environment at some point of assembly thus leading one of ordinary skill in the art to use two filters (one on each entrance to a component) that trap whatever bacteria exists between them. Filters however capable of trapping such bacteria are of a small pore size (generally 0.22 micron or 0.1 micron) and would inhibit flow of most liquids without some pressurization. Likewise, many fluids are known to foul or clog these filters over the use of the filters making the transfer even more difficult and limited. Lastly, they would prevent any larger molecules from passing through them, therefore limiting the use of such a device to small molecules or liquids only. The present invention overcomes all these disadvantages.

No basis has been provided for any suggestion or motivation in the cited reference to modify it such that the present invention as claimed would be arrived at. See *In re Rouffet*, 47 U.S. P.Q.2d 1453, 1457-58 (Fed. Cir. 1998) ("To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons

that the skilled artisan, confronted with the same problems as the inventor and with knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed."). No motivation has been provided as to why the skilled artisan would modify the valve of the reference by a sterile plug as claimed. It is well settled that to establish a *prima facie* case of obviousness, the prior art must teach or suggest all the limitations of a claim, there must exist a suggestion or motivation in the reference itself or as a matter of general knowledge to modify the reference, and there must be a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Applicants respectfully submit that a *prima facie* case of obviousness has not been established in this instance.

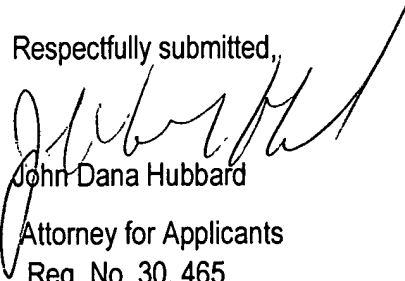
Additionally, the coupler also contains a stem that is capable of moving into and through the open port of the connector when assembled. This ensures that there is a sterile pathway through the device when used. It also helps to lock the components together making their accidental removal unlikely. The cited reference fails to teach or suggest this element as well. One of ordinary skill in the art would not have any suggestion or motivation to use such a stem from the teachings of the reference or as a matter of general knowledge to modify the reference. Applicants respectfully submit that a *prima facie* case of obviousness has not been established in this instance.

Appl No 10/626,282
Amdt dated June 2, 2006
Reply to Office Action of April 4, 2006



The present response and amendment place the claims in condition for allowance or at least present the claims in a better position for appeal and entrance of the response and amendment is respectfully requested.

Respectfully submitted,

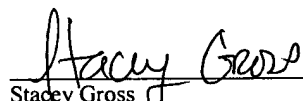

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